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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
WIEKER, AMANDA FLYNN	
ART UNIT	**PAPER NUMBER**
3743	

DATE MAILED: 06/27/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/839,643	KEREN ET AL.	
	Examiner	Art Unit	
	Amanda F. Wieker	3743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 May 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *32-58* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *32-58* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *9/28/04* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 31 May 2005 has been entered.

Drawings

2. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the subject matter of claims 35 and 50 (two fixation elements at each end) must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the

applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

3. The amendment filed 05 April 2005 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: The subject matter of claims 35 and 50 is not supported by the specification as originally filed. The specification and drawings do not disclose that the tubular element includes two ends wherein two of said fixation elements are disposed at each of said ends. The application as filed does not provide support for two fixation elements per end.

Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Objections

4. Claims 34 and 50 are objected to because of the following informalities:

Claim 34 is missing a period.

In claim 50 at line 1, it appears that the term "including" should be replaced with --includes--.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

5. Claims 35 and 50 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the

relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

As discussed above, the specification as originally filed did not disclose two fixation elements at each end of the tubular element. The specification only disclosed one fixation element (110) per end. As such, these claims constitute new matter.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. Claims 32-36 and 54-58 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent Number 6,458,153 to Bailey et al.

Bailey et al. disclose an apparatus (40) for decreasing pressure in a first chamber of the heart, the apparatus comprising a shunt including a fixation element (42, 44), a shunt tube element (11, 12) and a valve element (28), said valve element adapted to selectively permit blood flow between the first chamber and a second chamber at a pre-selected pressure differential threshold (at a "positive pressure" that overcomes the bias exerted by the valve, to allow flow from LA toward LV; see column 8, lines 1-4 and column 11, lines 13-27). Flow is selectively permitted when a pressure differential exists between the first and second chambers,

wherein the pressure differential is between a lower (zero) and higher ("positive pressure" enough to overcome valve's bias) threshold.

The tubular element includes two ends and two tissue fixation elements (42, 44) at each of the ends, said elements including shape-retaining metallic material.

Bailey et al. further disclose the step of implanting of the shunt using a catheter (200, 501), in a percutaneous procedure.

The valve member of the shunt tube comprises at least one flat pivoting plate (leaflets 26).

The device disclosed by Bailey et al. is fully capable of being placed across the atrial septum, or any other desired region of the heart, to provide blood flow between the left and right atria, and to control atrial pressure.

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 32-34, 36 and 54-58 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent Number 5,429,144 to Wilk.

Wilk discloses an apparatus for decreasing blood pressure in a first chamber of a heart comprising a shunt including a fixation element ("spring bias or memory"), a shunt tube element (66), and a valve element (68), said valve element adapted to enable selectively permitting blood flow between the first chamber and a second chamber of the heart at a pre-selected pressure differential threshold, wherein the pressure differential threshold is that

pressure which occurs at maximum systole, due to maximum contraction of the muscles of the left ventricle which overcomes the opposing pressure in the second chamber. Due to the increased pressure caused by the systolic contraction, the blood contained in the left ventricle is imparted with a higher pressure, which causes it to flow out the one-way valve, and into the second chamber.

The tubular element includes two ends and a tissue fixation element disposed at each end, said elements including shape-retaining metallic material.

Wilk discloses implanting said shunt using a catheter in a percutaneous procedure.

Wilk discloses that the shunt tube further comprises at least one flat pivoting plate (68).

The device disclosed by Wilk is fully capable of being placed across the atrial septum, or any other desired region of the heart, to provide blood flow between the left and right atria, and to control atrial pressure.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

11. Claims 41-44 and 48-53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bailey et al.

Bailey et al. disclose the previously described shunt, which is structurally identical to that claimed. The shunt includes at least two fixation elements (42, 44), a shunt tube element (11,

12) and a valve element (28), said valve element adapted to selectively permit blood flow between a first chamber and a second chamber at a pre-selected pressure differential threshold.

The shunt disclosed by Bailey et al. is fully capable of being implanted between any two chambers of the heart, including between the left and right atria. Note that Bailey et al. disclose the shunt as a "Chamber-to-Chamber Configuration".

The claimed method of decreasing blood pressure in a first atrium of the heart would have been obvious to one skilled in the art at the time the invention was made, by the use of the shunt disclosed by Bailey et al., which is fully structurally capable of decreasing blood pressure in any chamber of the heart.

12. Claims 41-44, 48-49, 51-53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wilk.

Wilk discloses the previously described shunt, which is structurally identical to that claimed. The shunt includes a fixation element, a shunt tube element (66), and a valve element (68), said valve element adapted to enable selectively permitting blood flow between the first chamber and a second chamber of the heart at a pre-selected pressure differential threshold.

The shunt disclosed by Wilk is fully capable of being implanted between any two chambers of the heart, including between the left and right atria.

The claimed method of decreasing blood pressure in a first atrium of the heart would have been obvious to one skilled in the art at the time the invention was made, by the use of the shunt disclosed by Wilk, which is fully structurally capable of decreasing blood pressure in any chamber of the heart.

13. Claims 37, 39-40, 45 and 47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bailey et al. in view of U.S. Patent Number 6,210,318 to Lederman.

Bailey et al. disclose the previously described shunt capable of communicating blood from a first atrium to a second atrium, to reduce pressure as blood flows through the shunt. Bailey et al. specify that the shunt may have a one-way valve to permit flow from the first chamber. Bailey et al. do not specify that the valve be a semi-passive check valve. Bailey et al. also do not specify that the shunt include pumping means.

Lederman discloses a shunt and pumping balloon device that is placed in a first chamber of a patient's heart, to assist in the pumping of blood from the first chamber. The device comprises several valves, which may be semi-passive check valves operated by an extracorporeal controller and energy source to control the activation of the valves externally from the patient. The pumping balloon (102) is in fluid communication with the shunt (104) and has an input connected to the first chamber, and an output connected to a volume of lower pressure.

It would have been obvious to one skilled in the art at the time the invention was made to have provided the shunt disclosed by Bailey et al., wherein the valve is a semi-passive check valve and the shunt includes a pump, as taught by Lederman, to control activation of the valves externally from the patient, and to assist the flow of blood from the first chamber. The claimed method of decreasing blood pressure in a first atrium is made obvious by the use of the Bailey et al. device in view of Lederman, which is fully capable of decreasing blood pressure in any chamber of the heart.

14. Claims 38 and 46 rejected under 35 U.S.C. 103(a) as being unpatentable over Bailey et al. in view of U.S. Patent Number 6,632,169 to Korakianitis et al.

Bailey et al. disclose the previously described shunt capable of communicating blood from a first atrium to a second atrium, to reduce pressure as blood flows through the shunt.

Bailey et al. specify that the shunt may have a one-way valve to permit flow from the first chamber. Bailey et al. do not specify that the valve be a semi-passive check valve.

Korakianitis et al. disclose a left ventricular assist device that is placed in a first chamber of a patient's heart, to assist in the pumping of blood through the heart and body. The device comprises a semi-passive check valve operated by an intra-corporeal electrical battery such that the entire device can be contained within the body.

It would have been obvious to one skilled in the art at the time the invention was made to have provided the shunt disclosed by Bailey et al., wherein the valve is a semi-passive check valve, as taught by Korakianitis et al., such that the entire device can be contained within the body. The claimed method of decreasing blood pressure in a first atrium is made obvious by the use of the Bailey et al. device in view of Korakianitis et al., which is fully capable of decreasing blood pressure in any chamber of the heart.

15. Claims 37, 39-40, 45 and 47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wilk in view of U.S. Patent Number 6,210,318 to Lederman.

Wilk discloses the previously described shunt capable of communicating blood from a first atrium to a second atrium, to reduce pressure as blood flows through the shunt. Wilk specifies that the shunt may have a one-way valve to permit flow from the first chamber. Wilk does not specify that the valve be a semi-passive check valve. Wilk also does not specify that the shunt include pumping means.

Lederman discloses a shunt and pumping balloon device that is placed in a patient's left ventricle, to assist in the pumping of blood from the ventricle. The device comprises several valves, which may be semi-passive check valves operated by an extracorporeal controller and energy source to control the activation of the valves externally from the patient. The pumping

balloon (102) is in fluid communication with the shunt (104) and has an input connected to the left ventricle, and an output connected to a volume of lower pressure.

It would have been obvious to one skilled in the art at the time the invention was made to have provided the shunt disclosed by Wilk wherein the valve is a semi-passive check valve and the shunt includes a pump, as taught by Lederman, to control activation of the valves externally from the patient, and to assist the flow of blood from the first chamber. The claimed method of decreasing blood pressure in a first atrium is made obvious by the use of the Wilk device in view of Lederman, which is fully capable of decreasing blood pressure in any chamber of the heart.

16. Claims 38 and 46 rejected under 35 U.S.C. 103(a) as being unpatentable over Wilk in view of U.S. Patent Number 6,632,169 to Korakianitis et al.

Wilk discloses the previously described shunt capable of communicating blood from a first atrium to a second atrium, to reduce pressure as blood flows through the shunt. Wilk specifies that the shunt may have a one-way valve to permit flow from the first chamber. Wilk does not specify that the check valve be a semi-passive check valve.

Korakianitis et al. disclose a left ventricular assist device that is placed in a patient's left ventricle, to assist in the pumping of blood through the heart and body. The device comprises a semi-passive check valve operated by an intra-corporeal electrical battery such that the entire device can be contained within the body.

It would have been obvious to one skilled in the art at the time the invention was made to have provided the shunt disclosed by Wilk wherein the check valve is a semi-passive check valve, as taught by Korakianitis et al., such that the entire device can be contained within the body. The claimed method of decreasing blood pressure in a first atrium is made obvious by the

use of the Wilk device in view of Korakianitis et al., which is fully capable of decreasing blood pressure in any chamber of the heart.

Response to Arguments

17. Applicant's arguments with respect to claims 32-58 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amanda F. Wieker whose telephone number is 571-272-4794. The examiner can normally be reached on Monday-Thursday, 7:30 - 5:00 and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry Bennett can be reached on 571-272-4791. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Amanda F. Wieker
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